

REMARKS

This Response is submitted in reply to the final Office Action mailed on February 6, 2009. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-504 on the account statement.

Claims 1, 3 and 5-14 are pending in the application. Claims 2 and 4 were previously canceled. In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §112; Claims 1, 5-7 and 9 are rejected under 35 U.S.C. §102(b) and Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a). In response, Claims 1 and 11 are amended. The amendments do not add new matter and are supported in Applicants' specification at page 11, lines 19-25. In view of the amendments and for at least the reasons provided below, Applicants respectfully request that the rejections be withdrawn.

In the Office Action, Claims 11-12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that the Applicants' specification does not support the previous amendment to Claim 11, particularly the steps of mixing microorganisms and inert carbohydrate followed by drying and adding further components. Applicants respectfully disagree and submit that the specification provides support for the above claim language. Applicants' specification states that the present invention provides a process for obtaining a pellet, which comprises mixing a preparation of "microorganisms" and "further components", drying the mixture to an Aw below 0.3, compacting the mixture under pressure to obtain pellets comprising a volume of at least 0.02 cm³, and coating the pellets with a moisture barrier. See, specification, page 4, line 35 to page 5, line 3. The specification also states that the "microorganisms" are preferably in the form of particles, that the particles preferably comprise inert carbohydrates and that suitable particles are obtained by mixing the microorganisms and inert carbohydrates. See, specification, page 11, lines 14-33. Therefore, the specification establishes that particles containing "microorganisms" can include inert carbohydrates and can be dried. The specification also establishes that the "microorganisms," preferably in the form of dried particles, can be mixed with "further components" and dried to the water activity and volume required in Claim 11. Accordingly,

Applicants submit that the specification provides sufficient support for the elements recited in Claim 11.

In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action asserts that the phrase “inert carbohydrate” makes the claim indefinite because it is unclear what is meant by inert carbohydrate. In response, Applicants amend independent Claims 1 and 11 to recite, in part, at least one inert carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof. The amendment is supported in Applicants’ specification at page 11, lines 19-25. In view of this amendment to Claims 1 and 11 to add a Markush group for the inert carbohydrate, Applicants submit that the phrase “inert carbohydrate” is not indefinite.

Accordingly, Applicants respectfully request that that 35 U.S.C. §112 rejections of Claims 1, 3 and 5-14 be withdrawn.

In the Office Action, Claims 1, 5-7 and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,480,641 to Casas-Perez (“*Casas*”). Amended independent Claim 1 recites, in part, a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate embedded with 10^5 to 10^8 viable micro-organisms per gram of pellet, wherein the inner matrix contains 40% to 70%, by weight of total dry matter, of the at least one inert carbohydrate, and the coating comprises a moisture barrier. The amendment is supported in Applicants’ specification at page 11, lines 19-25. Applicants submit that *Casas* fails to disclose or suggest every element of Claims 1, 5-7 and 9.

Casas fails to disclose or suggest a pellet comprising a compacted inner matrix and at least one coating wherein the inner matrix contains 40% to 70%, by weight of total dry matter, of at least one inert carbohydrate as required, in part, by independent Claim 1. In fact, *Casas* fails to disclose any dry weight percentages of its whey in its compressed pellet. At best, *Casas* suggests 100% dry weight of whey in a pellet of the first embodiment where no other components are present in the pellet. The second embodiment, on the other hand, includes *L. reuteri* cells suspended in oil and mixed with whey. However, *Casas* fails to teach or suggest

any dry weight percentages of the whey in that embodiment as well. Therefore, *Casas* is deficient with respect to independent Claim 1.

Casas also fails to disclose or suggest a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate and viable micro-organisms, and the coating comprises a moisture barrier as required, in part, by independent Claim 1. Simply put, independent Claim 1 require (a) an inner matrix with microorganisms and an inert carbohydrate and (b) that inner matrix having a coating. In contrast to Examiner's assertions, *Casas* fails to teach this above combination of elements. *Casas* teaches two embodiments. The first includes pelletized whey particles, not mixed with any microorganisms, coated by microorganisms suspended in oil. This embodiment is deficient because it does not teach an inner matrix having both microorganisms and inert carbohydrates. The second embodiment includes a microorganism-oil suspension mixed with whey, with that mixture compressed into pellets with no coating. This embodiment is deficient because it does not teach a coating. The table below makes very clear the deficiencies in both embodiments of *Casas*.

Independent Claim 1	Embodiment 1 of <i>Casas</i>	Embodiment 2 of <i>Casas</i>
Inner Matrix comprising: a) microorganisms AND b) inert carbohydrates	NO – includes whey only	YES – includes microorganisms-in-oil suspension mixed with whey
Coating	YES – includes microorganisms suspended in oil	NO – no coating

Applicants submit that the Examiner is incorrectly combining embodiments of a prior art reference to arrive at the present claims. “[T]he prior art reference--in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Finisar Corp. v. DirectTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The “arranged as in the claim” language requires an anticipatory reference “to show all of the limitations of the claims arranged or *combined in the same way* as recited in the claims.” *Net Moneyin*, 545 F.3d at 1370 (emphasis added). The

Federal Circuit has similarly held that it is improper to pick and choose various elements that are not directly related to each other by the teachings of the reference. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008). Instead, elements from different embodiments of a single reference can be combined for anticipation purposes only if the reference teaches or suggests such combination to one of skill in the art. *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 724, 752 (D. Del. 2002). The two embodiments of *Casas* both teach the three specific components of whey, microorganisms and oil. To read on the present claims, the core of the second embodiment is necessary as it teaches a combination of microorganisms and whey (inert carbohydrate) required by the claims. However, the second embodiment uses no coating because every component, including oil, is already contained in the pellet core. The first embodiment, on the other hand, teaches a coating of microorganisms and oil, but contains such coating only because the pellet core solely contains whey. Therefore, there is no reason or suggestion to combine the pellet core of the second embodiment with the coating of the first embodiment because the core of the second embodiment already contains the microorganism-oil suspension. Moreover, the Examiner cites no support in *Casas* for combining the various elements from different embodiments. As such, Appellants respectfully submit that the combination of elements from different embodiments is insufficient to establish anticipation.

Accordingly, because *Casas* fails to disclose or suggest every element of independent Claim 1, Applicants respectfully request that the anticipation rejection of Claims 1, 5-7 and 9 be withdrawn.

In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,888,171 to Okonogi, et al. ("*Okonogi*") in view of EP 0 298 605 to Klapwijk, et al. ("*Klapwijk*") and WO 99/48372 to Van Lengerich ("*Van Lengerich*"). Applicants submit that the cited references, alone or in combination, fail to disclose or suggest every element of the present claims.

Okonogi, *Klapwijk* and *Van Lengerich* fail to disclose or suggest a pellet comprising an inner matrix comprising at least one inert carbohydrate embedded with 10^5 to 10^8 viable micro-organisms per gram of pellet as required, in part, by amended independent Claim 1. *Okonogi*, *Klapwijk* and *Van Lengerich* also fail to disclose or suggest a process for obtaining pellets comprising mixing a first preparation of micro-organisms and at least one inert carbohydrate,

wherein the micro-organisms are embedded in the at least one inert carbohydrate as required, in part, by amended independent Claim 11. Instead, *Okonogi* teaches a granular product consisting of a core material and an adherent material containing dried microorganism cells and binding material for coating said core material with said adherent material (including microorganisms) in a stratified structure. See, *Okonogi*, column 3, lines 1-5. Therefore, rather than teaching carbohydrates embedded with microorganisms, *Okonogi* teaches coating a core with adherent microorganism material.

Applicants submit that secondary references *Klapwijk* and *Van Lengerich* fail to remedy the above deficiencies in *Okonogi*. *Klapwijk*, for example, is entirely directed toward aqueous suspensions of viable microflora that have improved ambient stability and is usable in fermentation. See, *Klapwijk*, Abstract. In fact, *Klapwijk* fails to even teach or disclose a pellet composition or process for obtaining a pellet. Instead, the composition of *Klapwijk*, consisting of a microorganism slurry and flour, is combined and packaged as a finished product for use generally in bread making. See, *Klapwijk*, page 3, lines 22-25 and Examples 1 and 2. *Van Lengerich* is entirely directed toward products having encapsulated organisms. See, *Van Lengerich*, Abstract. Specifically, the invention of *Van Lengerich* provides a product with an encapsulated microorganism in a pleasantly tasting and chewable surrounding matrix. As such, *Van Lengerich* clearly fails to teach or suggest carbohydrates embedded with microorganisms. Instead, *Van Lengerich* teaches the surrounding of encapsulated microorganisms. Therefore, Applicants respectfully submit that *Okonogi*, *Klapwijk* and *Van Lengerich* fail to disclose or suggest every element of the present claims.

Also in the Office Action, Claims 11-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Casas*. Amended independent Claim 11 recites, in part, mixing a preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one inert carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof. The amendment is supported in Applicants' specification at page 11, lines 19-25. Applicants submit that *Casas* fails to disclose or suggest every element of Claims 11-12.

Casas fails to disclose or suggest mixing a preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one inert carbohydrate as required, in part, by

independent Claim 11. In fact, *Casas* fails to disclose any dry weight percentages of its whey in its compressed pellet. At best, *Casas* suggests 100% dry weight of whey in a pellet of the first embodiment where no other components are present in the pellet. The second embodiment, on the other hand, includes *L. reuteri* cells suspended in oil mixed with whey. However, *Casas* fails to teach or suggest any dry weight percentages of the whey in that embodiment. Therefore, *Casas* is deficient with respect to independent Claim 11.

Accordingly, because the cited references fail to disclose or suggest every element of independent Claims 1 and 11, Applicants respectfully request that the obviousness rejections of Claims 1, 3 and 5-14 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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